



February 20, 2003

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## HOUSE BILL No. 1458

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DIGEST OF HB 1458 (Updated February 19, 2003 1:17 PM - DI 77)

**Citations Affected:** IC 12-15; noncode.

**Synopsis:** Medicaid prescription drugs. Provides that prior authorization is not required for a single source drug that is newly approved by the federal Food and Drug Administration (FDA) while the drug utilization review board (board) is determining if the drug should be on the preferred drug list. Allows the office of Medicaid policy and planning (OMPP) to add a drug that has been approved by the FDA to the preferred drug list without prior approval from the board. Permits the board to add a drug that has been approved by the FDA to the preferred drug list. (Current law allows: (1) OMPP to add only new single source drugs to the preferred drug list without prior approval of the board; and (2) the board to add only new single source drugs to the preferred drug list.) Allows OMPP to limit access to prescription drugs for prescription drug program recipients to prevent fraud and inappropriate utilization. Makes cross references.

**Effective:** Upon passage; July 1, 2003.

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January 15, 2003, read first time and referred to Committee on Public Health.  
February 19, 2003, amended, reported — Do Pass.

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HB 1458—LS 6678/DI 104+



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February 20, 2003

First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

## HOUSE BILL No. 1458

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

*Be it enacted by the General Assembly of the State of Indiana:*

1 SECTION 1. IC 12-15-35-28, AS AMENDED BY P.L.107-2002,  
2 SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
3 JULY 1, 2003]: Sec. 28. (a) The board has the following duties:

4 (1) The adoption of rules to carry out this chapter, in accordance  
5 with the provisions of IC 4-22-2 and subject to any office  
6 approval that is required by the federal Omnibus Budget  
7 Reconciliation Act of 1990 under Public Law 101-508 and its  
8 implementing regulations.

9 (2) The implementation of a Medicaid retrospective and  
10 prospective DUR program as outlined in this chapter, including  
11 the approval of software programs to be used by the pharmacist  
12 for prospective DUR and recommendations concerning the  
13 provisions of the contractual agreement between the state and any  
14 other entity that will be processing and reviewing Medicaid drug  
15 claims and profiles for the DUR program under this chapter.

16 (3) The development and application of the predetermined criteria  
17 and standards for appropriate prescribing to be used in

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retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review

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with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

- (A) Medicaid's fee for service program;
- (B) Medicaid's primary care case management program; and
- (C) the primary care case management component of the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

- (1) Use literature abstracting technology.
- (2) Use commonly accepted guidance principles of disease management.
- (3) Develop therapeutic classifications for the preferred drug list.
- (4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.
- (5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that ~~is not included on~~ **has been excluded from** the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date **on which the manufacturer notifies the board in writing** of the drug's approval. However, if the board determines that

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there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be ~~automatically~~ required for a single source drug that is newly approved by the federal Food and Drug Administration, ~~and that is:~~

(1) ~~in a therapeutic classification:~~

(A) ~~that has not been reviewed by the board; and~~

(B) ~~for which prior authorization is not required; or~~

(2) ~~the sole drug in a new therapeutic classification that has not been reviewed by the board.~~

**pending a determination by the board under this chapter.**

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) **Except as provided by IC 12-15-35.5-3(b)**, the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital

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costs or in other state funded programs as a result of the preferred drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 2. IC 12-15-35-28.7, AS ADDED BY P.L.107-2002, SECTION 19, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28.7. (a) The board shall submit the initial approved preferred drug list to the office not later than August 1, 2002.

(b) Except as permitted under subsection (g), the office may not further restrict the status of a drug in the Medicaid program or the children's health insurance program until the board reviews a therapeutic classification and the office implements the therapeutic classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) **Except as provided by section 28(g)(3) of this chapter**, the office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 3. IC 12-15-35-43.5, AS ADDED BY P.L.107-2002, SECTION 21, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 43.5. (a) The board, the therapeutics committee, or the office may not release proprietary or confidential information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.

(b) **Information described in subsection (a) is confidential for purposes of IC 5-14-3-4(a)(1).**



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SECTION 4. IC 12-15-35.5-2.5, AS ADDED BY P.L.107-2002, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except **to address situations described in IC 12-15-35-28(a)(8)(A) through (K)** and as provided under ~~IC 12-15-35-8~~ and section 7 of this chapter.

SECTION 5. P.L.107-2002, SECTION 36, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: SECTION 36. (a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning.

(b) The office shall develop a federal Medicaid waiver application under which a prescription drug program may be established or implemented to provide access to prescription drugs for low-income senior citizens.

(c) Before the office may submit an application for a federal Medicaid waiver that will have an effect on the Indiana prescription drug program established under IC 12-10-16, the following must occur:

- (1) The office shall submit the proposed Medicaid waiver to the prescription drug advisory committee established under this act.
- (2) The prescription drug advisory committee must review, allow public comment, and approve the proposed Medicaid waiver.

(d) A prescription drug program established or implemented by the office or a contractor of the office under this SECTION may **only not** limit access to prescription drugs for prescription drug program recipients, **except that:**

**(1) access may be limited** to the extent that restrictions are in place in the Medicaid program on the date of enactment of this act; **and**

**(2) access may be limited to prevent the following:**

- (A) Fraud.**
- (B) Abuse.**
- (C) Waste.**
- (D) Overutilization of prescription drugs.**
- (E) Inappropriate utilization of prescription drugs.**

(e) Changes to a prescription drug program that:

- (1) is established or implemented by the office or a contractor of the office under this SECTION; and
- (2) uses money from the Indiana prescription drug account established under IC 4-12-8-2;

must be approved by the prescription drug advisory committee



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1 established under this act.

2 (f) Before July 1, 2002, the office shall apply to the United States  
3 Department of Health and Human Services for approval of any waiver  
4 necessary under the federal Medicaid program to provide access to  
5 prescription drugs for low income senior citizens.

6 (g) A Medicaid waiver developed under this SECTION must limit  
7 a prescription drug program's state expenditures to funding  
8 appropriated to the Indiana prescription drug account established under  
9 IC 4-12-8-2 from the Indiana tobacco master settlement agreement  
10 fund.

11 (h) The office may not implement a waiver under this SECTION  
12 until the office files an affidavit with the governor attesting that the  
13 federal waiver applied for under this SECTION is in effect. The office  
14 shall file the affidavit under this subsection not later than five (5) days  
15 after the office is notified that the waiver is approved.

16 (i) If the office receives a waiver under this SECTION from the  
17 United States Department of Health and Human Services and the  
18 governor receives the affidavit filed under subsection (f), the office  
19 shall implement the waiver not more than sixty (60) days after the  
20 governor receives the affidavit.

21 SECTION 6. **An emergency is declared for this act.**

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## COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1458, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-15-35-28, AS AMENDED BY P.L.107-2002, SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28. (a) The board has the following duties:

- (1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.
- (2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.
- (3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.
- (4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.
- (5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.
- (6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:
  - (A) The Indiana board of pharmacy.

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- (B) The medical licensing board of Indiana.
- (C) The SURS staff.
- (7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.
- (8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:
  - (A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.
  - (B) Potential or actual severe or adverse reactions to drugs.
  - (C) Therapeutic appropriateness.
  - (D) Overutilization or underutilization.
  - (E) Appropriate use of generic drugs.
  - (F) Therapeutic duplication.
  - (G) Drug-disease contraindications.
  - (H) Drug-drug interactions.
  - (I) Incorrect drug dosage and duration of drug treatment.
  - (J) Drug allergy interactions.
  - (K) Clinical abuse and misuse.
- (9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.
- (10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.
- (11) The research, development, and approval of a preferred drug list for:
  - (A) Medicaid's fee for service program;
  - (B) Medicaid's primary care case management program; and
  - (C) the primary care case management component of the children's health insurance program under IC 12-17.6;
 in consultation with the therapeutics committee.
- (12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.
- (13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint

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commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

- (1) Use literature abstracting technology.
- (2) Use commonly accepted guidance principles of disease management.
- (3) Develop therapeutic classifications for the preferred drug list.
- (4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.
- (5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that ~~is not included on~~ **has been excluded from** the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date **on which the manufacturer notifies the board in writing** of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be ~~automatically~~ required for a single source drug that is newly approved by the federal Food and Drug Administration, ~~and that is:~~

~~(1) in a therapeutic classification:~~

~~(A) that has not been reviewed by the board; and~~

~~(B) for which prior authorization is not required; or~~

~~(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.~~

**pending a determination by the board under this chapter.**

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list

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developed under subsection (a)(11):

(1) **Except as provided by IC 12-15-35.5-3(b)**, the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

- (A) To override a prospective drug utilization review alert.
- (B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.
- (C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.
- (D) To permit implementation of a disease management program.
- (E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

- (1) The cost of administering the preferred drug list.
- (2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.
- (3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.
- (4) The number of times prior authorization was requested, and the number of times prior authorization was:
  - (A) approved; and
  - (B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 2. IC 12-15-35-28.7, AS ADDED BY P.L.107-2002, SECTION 19, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28.7. (a) The board shall submit the initial approved preferred drug list to the office not later than August 1, 2002.



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(b) Except as permitted under subsection (g), the office may not further restrict the status of a drug in the Medicaid program or the children's health insurance program until the board reviews a therapeutic classification and the office implements the therapeutic classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) **Except as provided by section 28(g)(3) of this chapter**, the office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 3. IC 12-15-35-43.5, AS ADDED BY P.L.107-2002, SECTION 21, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 43.5. **(a)** The board, the therapeutics committee, or the office may not release proprietary or confidential information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.

**(b) Information described in subsection (a) is confidential for purposes of IC 5-14-3-4(a)(1).**

SECTION 4. IC 12-15-35.5-2.5, AS ADDED BY P.L.107-2002, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except **to address situations described in IC 12-15-35-28(a)(8)(A) through (K) and** as provided under ~~IC 12-15-35-8~~ and section 7 of this chapter."

Page 2, line 5, after "act;" insert "**and**".

Page 2, line 11, delete "; and" and insert ".".

Page 2, delete lines 12 through 13.

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Renumber all SECTIONS consecutively.  
and when so amended that said bill do pass.  
(Reference is to HB 1458 as introduced.)

BROWN C, Chair

Committee Vote: yeas 10, nays 0.

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